



**Pipeline and Hazardous Materials Safety Administration
Office of Pipeline Safety**

Substance Abuse Program:

Comprehensive Audit and Inspection Protocol Form

Specimen Collection Sites

Form No.: 3.1.7

January 29, 2010

Protocol Area O: Specimen Collection Sites

Service Provider Profile and General Audit Information

Company Name of Service Provider:	Clinical Collection Management, Inc.		
Official Address	8730 Big Bend, Suite A, St. Louis, MO 63119		
Business Tax ID Number	Ameren Services BTIN N0.43-1799279		
Operator/Contractor Name and Op ID or Business Tax ID number utilizing the above Service Provider:	Ameren Op ID No.-32513		
Operator's/Contractor's DER or Substance Abuse Program Mgr /:	Karan Henderson and Linda Gudorp		Phone No.: 314-554-4047 and 314-554-3307
Service Provider Company Contact Information		Service Provider's Official Representative Contact	
Doing Business As or Affiliated Company Name	Clinical Collection Management, Inc.	Contact Name:	Thomas (Tom) Fetting
Ph. No.:	314-963-9404	Ph. No.:	314-963-3404 ext.100
Fax No.:	314-963-3406	Fax No.:	314-963-3406
Web Site or Email	http://www.ccm-drugtest.com/	Email	thomas@ccm-drugtest.com
Mailing Address: (If different from official address)	Same as above	Lead Auditor or Inspector:	Name: Valerie Schwing
			Agency: Illinois Commerce Commission
		Date of Audit or Inspection:	July 24, 2015
Technician Interviewed	Qualification Expiration Date	Telephone Number	Comment
Jason Hamilton	March 4, 2019		

Key Persons	Name/Title	Phone/Email Address
Primary Service Provider Representative Interviewed or Providing Information	Karan Henderson and Linda Gudorp	314-554-4047 khenderson@ameren.com 314-554-3307
Others Interviewed, Providing Information or Present at Audit:		

PHMSA and State Representatives Participating:

Name/Title	Office/Organization	Email Address
Valerie Schwing/Pipeline Safety Analyst	Illinois Commerce Commission	

Contact Information:

Any questions or requests for guidance related to this audit protocol document should contact:

Stanley T. Kastanas, Director

Office of Substance Abuse Policy, Investigations and Compliance

Pipeline and Hazardous Materials Safety Administration (PHMSA)-Pipeline Safety (OPS)

Washington, DC 20590

Contact Number: 202-550-0629

E-mail Address: Stanley.Kastanas@DOT.GOV

Auditor Notes and Additional Information:

This image shows a single sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.

- [O.01 Urine Collection Personnel](#)
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O.01 Urine Collection Personnel

Verify that training and usage of personnel is in compliance with the applicable requirements of Part 40.

O.01.a. Does the operator ensure that, unless no other collector is available, an immediate supervisor of an employee does not serve as a collection site person [§40.31(c)]?

O.01.a. Inspection Results (type an X in exactly one cell below)		Inspection Notes
X	No Issue Identified	Jason Hamilton On Site Collector Certification on March 4, 2014. Jason Hamilton Breath Alcohol Technician on March 4, 2014. Staff verified with Jason Hamilton that unless no other collector is available, an immediate supervisor of an employee does not serve as a collection site person
	Potential Issue Identified (explain)	
	N/A (explain)	
	Not Inspected	

O.01.b. Do collectors meet the training requirements of §40.33 and is documentation available showing that currently all requirements are met [§40.33(g)]?

O.01.b. Inspection Results (type an X in exactly one cell below)		Inspection Notes
X	No Issue Identified	Jason Hamilton On Site Collector Certification on March 4, 2014. Jason Hamilton Breath Alcohol Technician on March 4, 2014.
	Potential Issue Identified (explain)	
	N/A (explain)	
	Not Inspected	

O.01.c. Does the operator provide error correction training as required by §40.33(f) and does the training occur within 30 days of the date of notification of the error that led to the need for training?

O.01.c. Inspection Results (type an X in exactly one cell below)		Inspection Notes
X	No Issue Identified	Staff reviewed the Urine Specimen Collection Guidance provided by Jason Hamilton.
	Potential Issue Identified (explain)	
	N/A (explain)	
	Not Inspected	

O.02 Collection Sites, Forms and Supplies

Verify that collection sites, forms and supplies are in compliance with the applicable physical and security requirements of Part 40.

O.02.a. Has the employer designated a collection site that meets the requirements of §40.41.

O.02.a. Inspection Results (type an X in exactly one cell below)		Inspection Notes
X	No Issue Identified	Staff examined the collection site at Belleville, IL. The site was in compliance with the applicable physical and security requirements of Part 40.
	Potential Issue Identified (explain)	
	N/A (explain)	
	Not Inspected	

O.02.b. If the collection site uses a facility normally used for other purposes, are procedures in place to ensure before the collection that: (1) access to collection materials and specimens is effectively restricted; and (2) the facility is secured against access during the procedure to ensure privacy to the employee and prevent distraction of the collector? Also, are limited-access signs posted [§40.43(c)]?

O.02.b. Inspection Results (type an X in exactly one cell below)		Inspection Notes
X	No Issue Identified	Staff observed the collection site at Belleville, IL. The site was in compliance with the applicable physical and security requirements of Part 40. Signs were posted.
	Potential Issue Identified (explain)	
	N/A (explain)	
	Not Inspected	

O.02.c. Are procedures in place to assure the collector maintains personal control over each specimen and CCF throughout the collection process and to prevent unauthorized personnel from entering any part of the site in which urine specimens are collected or stored [§40.43(d)(5) and §40.43(e)]?

O.02.c. Inspection Results (type an X in exactly one cell below)		Inspection Notes
X	No Issue Identified	Staff reviewed the procedures in place to assure the collector maintains personal control over each specimen and CCF throughout the collection process and to prevent unauthorized personnel from entering any part of the site in which urine specimens are collected.
	Potential Issue Identified (explain)	
	N/A (explain)	
	Not Inspected	

O.02.d. Is the current Federal Drug Testing Custody and Control Form (CCF) or equivalent being used [§40.45]?

O.02.d. Inspection Results (type an X in exactly one cell below)		Inspection Notes
X	No Issue Identified	Staff examined the collector's current Federal Drug Testing Custody and Control Form "(CCF)".
	Potential Issue Identified (explain)	
	N/A (explain)	
	Not Inspected	

O.02.e. Is a collection kit used that meets the requirements of Appendix A to Part 40 [§40.49]?

O.02.e. Inspection Results (type an X in exactly one cell below)		Inspection Notes
X	No Issue Identified	Staff examined the collection kit used that meets the requirements of Appendix A to Part 40.
	Potential Issue Identified (explain)	
	N/A (explain)	
	Not Inspected	

O.03 Urine Specimen Collections

Verify that procedures for collection of urine specimens are in compliance with the applicable requirements of Part 40.

O.03.a. Do collection site personnel explain the basic collection procedure to the employee, including showing the employee the instructions on the back of the CCF [§40.61(e)]?

O.03.a. Inspection Results (type an X in exactly one cell below)		Inspection Notes
X	No Issue Identified	The collection site personnel did explain the basic collection procedure to the employee, including showing the employee the instructions on the back of the CCF.
	Potential Issue Identified (explain)	
	N/A (explain)	
	Not Inspected	

O.03.b. Do collection site personnel provide the donor with an individually wrapped or sealed collection container from the collection kit materials [§40.63(c)]?

O.03.b. Inspection Results (type an X in exactly one cell below)		Inspection Notes
X	No Issue Identified	The collection site personnel did demonstrate that he provides the donor with an individually wrapped or sealed collection container from the collection kit materials.
	Potential Issue Identified (explain)	
	N/A (explain)	
	Not Inspected	

O.03.c. Are precautions taken to ensure that unadulterated specimens are obtained and correctly identified that meet the following requirements:

- Bluing agents in toilet tank and all water sources secure [§40.43(b)(1) and (2)]
- Individual positively identified (photo ID, etc.) [§40.61(c)]
- Proper authority contacted if individual fails to arrive at the assigned time [§40.61(a)]
- The donor shall remove any unnecessary outer garments. Purses or briefcases shall remain with outer garments [§40.61(f)].
- Donor shall wash and dry his/her hands [§40.63(b)].
- To the greatest extent possible, the collector must keep an employee's collection container within view of both himself/herself and the employee between the time the employee has urinated and the specimen is sealed [§40.43(d)(2)]
- Any unusual behavior noted on the CCF [§40.63(e)]

O.03.c. Inspection Results (type an X in exactly one cell below)		Inspection Notes
X	No Issue Identified	<p>Staff observed bluing agents in toilet tank and all water sources secure [§40.43(b)(1) and (2)].</p> <p>The collection site personnel explained individual positively identified process (photo ID, etc.) [§40.61(c)].</p> <p>The collection site personnel explained the proper authority to contact if an individual failed to arrive at the assigned time. [§40.61(a)]</p> <p>The collection site personnel explained the donor shall remove any unnecessary outer garments. Purses or briefcases shall remain with outer garments. [§40.61(f)]</p> <p>The collection site personnel explained the donor washes and dries his/her hands. [§40.63(b)]</p> <p>The collector explained/demonstrated that he keeps an employee's collection container within view of both himself and the employee between the time the employee has urinated and the specimen is sealed. [§40.43(d)(2)]</p> <p>The collector explained unusual behaviors and how to note it on the CCF. [§40.63(e)]</p>
	Potential Issue Identified (explain)	
	N/A (explain)	
	Not Inspected	

O.03.d. Are procedures being followed at the collection site after the specimen has been provided in compliance with the requirements of §40.65

O.03.d. Inspection Results (type an X in exactly one cell below)		Inspection Notes
X	No Issue Identified	<p>Staff verified that procedures are being followed at the collection site after the specimen has been provided in compliance with the requirements of §40.65.</p>
	Potential Issue Identified (explain)	
	N/A (explain)	
	Not Inspected	

O.03.e. Have provisions been made if the donor is unable to provide at least 45 milliliters of urine [§40.65(a)]?

O.03.e. Inspection Results (type an X in exactly one cell below)		Inspection Notes
X	No Issue Identified	<p>Staff verified provisions have been made if the donor is unable to provide at least 45 milliliters of urine.</p>
	Potential Issue Identified (explain)	
	N/A (explain)	
	Not Inspected	

O.03.f. Are procedures in place for immediately collecting urine specimens under direct observation for the situations identified in §40.67(c)

1. As of August 31, 2009, verify that all collections for return-to-duty and follow-up testing were performed under DER directed direct observation [§40.67(b)]

O.03.f. Inspection Results (type an X in exactly one cell below)		Inspection Notes
X	No Issue Identified	Staff had the collector describe when directed direct observation would be necessary. The collector correctly listed off the situations.
	Potential Issue Identified (explain)	
	N/A (explain)	
	Not Inspected	

O.03.g. Are same gender collection personnel used if a collection is monitored under direct observation by non-medical personnel [§40.69(g)]

O.03.g. Inspection Results (type an X in exactly one cell below)		Inspection Notes
X	No Issue Identified	Staff varied that same gender collection personnel is used if a collection is monitored under direct observation by non-medical personnel.
	Potential Issue Identified (explain)	
	N/A (explain)	
	Not Inspected	

O.03.h. Is the CCF properly executed by authorized collection site personnel upon receipt and transfer of a urine specimen [§40.73(a)]

O.03.h. Inspection Results (type an X in exactly one cell below)		Inspection Notes
X	No Issue Identified	Staff verified the CCF is properly executed by authorized collection site personnel upon receipt and transfer of a urine specimen.
	Potential Issue Identified (explain)	
	N/A (explain)	
	Not Inspected	

Protocol Area O - Documents Reviewed			
Document Number	Rev	Date	Document Title

